REMARKS

Applicant respectfully requests reconsideration. Claims 63, 69-71, 136-138 and 140 were previously pending in this application. Claims 1, 10, 34, 42, 49, 53, 73, 84, 90, 107 and 116 are withdrawn from consideration as drawn to a non-elected invention. No claims are cancelled. Claims 63 and 71 have been amended. Support for the amendments is found at least on page 2 lines 32-33, page 11 lines 25-26, page 18 lines 16-25, and page 19 lines 13-27, and Figure 2. As a result, claims 63, 69-71 and 134-140 are pending for examination with claims 63 and 71 being independent claims. No new matter has been added.

Newly Added Claims

The Examiner has raised an objection to newly added claims 134, 135 and 139 on the grounds that they are directed to an invention that is independent or distinct from the invention originally claimed. Applicant respectfully disagrees.

Elected Group VII includes claims 63 and 69-71 which recite SEQ ID NO:1 and SEQ ID NO:2. Claim 63 embraces, inter alia, an isolated nucleic acid molecule comprising SEQ ID NO:1. Claim 71 embraces, inter alia, an isolated nucleic acid molecule that is a fragment of SEQ ID NO:1. The Examiner did not request a nucleic acid species election in the Restriction Requirement.

The scope of dependent claims 134, 135 and 139 falls within that of claims 63 and 71. For example, claim 134 recites an isolated nucleic acid molecule comprising SEQ ID NO:1, and claims 135 and 139 recite an isolated nucleic acid molecule comprising a particular fragment of SEQ ID NO:1. The Examiner has already searched SEQ ID NO:1 and fragments thereof in order to examine claims 63 and claim 71. No additional search for claims 134, 135 and 139 is necessary because the scope of those claims is contained within the search for claims 63 and 71. No additional burden is placed on the Examiner relating to the examination of these claims. For at least these reasons, claims 134, 135 and 139 should be examined as part of elected Group.

Reconsideration and withdrawal of this objection is respectfully requested.

Withdrawn Rejections

Applicant acknowledges and thanks the Examiner for the withdrawal of the objection to the title. Applicant also acknowledges the withdrawal of the rejection of claims 63, 69 and 70 under 35 U.S.C. § 102(b) as being anticipated by Pier *et al.*, the rejection of claim 71 under 35 U.S.C. § 102(b) as being anticipated by Cramton *et al.*, and the rejection of claims 63 and 69-71 under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 112

Indefiniteness

Claims 63, 69-71, 136-138 and 140 are rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. According to the Examiner, claims 63 and 71 are vague and indefinite for reciting the phrase "*ica* locus" and "*ica* nucleic acid" because the specific nucleotide sequence and structure and the encoded proteins and/or enzymes and their identities have not been defined and recited in the claim.

Applicant respectfully disagrees in part. As stated in the MPEP § 2173.02:

"Definiteness of claim language must be analyzed, not in a vacuum, but in light of:
(A) The content of the particular application disclosure;
(B) The teachings of the prior art; and
(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made."

Applicant has amended the claim to remove the recitation of "ica locus". Applicant has further amended the claim to recite an ica nucleic acid that comprises nucleotides 2330-5745 of SEQ ID NO:3 (GenBank Accession No. AF086783) that encode IcaA, IcaD, IcaB and IcaC. Support for this amendment can be found at least on page 11 lines 25-26, page 12 lines 28-30, page 18 lines 20-25, and page 19 lines 13-27, and Figure 2. The specification makes clear that an ica nucleic acid comprises one or more of the icaA, icaD, icaB and icaC genes, and the specification provides the nucleotide sequences of these genes (see SEQ ID NO:3 and GenBank Accession No. AF086783). One of ordinary skill in the art could readily understand and be able to determine the sequence of the ica nucleic acid as recited in claims 63 and 71 based on the teaching in the specification and the knowledge in the art at the time of filing.

The Examiner states that "it is unclear as to what specific enzymes and/or proteins are enhanced that result in the overproduction of any polysaccharides". Respectfully, the clarity of the claim should not depend on a recitation of the mechanism by which the claimed nucleic acids exert their effect. The claimed invention relates to structurally and functionally defined nucleic acids. The functional definition relates to the ability of these nucleic acids to enhance poly-N-acetyl glucosamine production when operably linked to a nucleic acid that encodes IcaA, IcaD, IcaB and IcaC, compared to poly-N-acetyl glucosamine production when SEQ ID NO:2 is operably linked to the same nucleic acid. As stated above, a person of ordinary skill will understand the meaning of, and more importantly is provided with, a nucleic acid that encodes IcaA, IcaD, IcaB and IcaC by the specification and the knowledge in the art. A person of ordinary skill will also understand the meaning of IcaA, IcaD, IcaB and IcaC based on the teaching in the specification and the knowledge in the art. The definiteness of the claim does not rest on an elaboration in the claim of the mechanism by which poly-N-acetyl glucosamine production is enhanced by operably linking the claimed nucleic acids to the ica nucleic acid. The claims are therefore definite.

Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Enablement

Claims 63, 69-71, 136-138 and 140 are rejected under 35 U.S.C. § 112, first paragraph, enablement. The claims are rejected because, according to the Examiner, "the claims recite the phrase "ica locus" and "ica nucleic acid", but do not recite the specific enzyme and/or proteins involved in polysaccharide production and the specific polysaccharide that is overproduced when the claimed nucleic acid molecule is operably linked to ica nucleic acid". Furthermore the Examiner states that "it is unclear as to what specific enzyme and/or proteins are enhanced that result in the overproduction of any polysaccharides".

Applicant respectfully disagrees in part. Claims 63 and 71 have been amended to recite that the polysaccharide is poly-N-acetyl glucosamine, to remove reference to the ica locus, and to recite that the ica nucleic acid encodes IcaA, IcaD, IcaB, and IcaC and has a sequence found in SEQ ID NO:3.

Applicant previously presented a full analysis of the Wands factors in response to this rejection (see Response to Office Action dated May 21, 2007, pages 10-15). The Examiner has presented only a limited analysis of the "nature and breadth of the claims" and the guidance and working examples as a rebuttal to the full analysis provided by the Applicant. In the interest of furthering prosecution, Applicant has presented arguments addressing the issues raised by the Examiner and respectfully refers the Examiner to Applicant's previous Wands analysis.

Applicant has identified and disclosed the genetic basis for the overproduction of poly-N-acetyl glucosamine observed in some bacterial strains. This observed overproduction is the result of mutations in the ica promoter sequence. The invention provides in part mutant ica promoter nucleic acids. The wild type promoter sequence is provided as SEQ ID NO:2. The claimed nucleic acids comprise a mutation of a 5 nucleotide span within this sequence, in whole or in part. The location of the 5 nucleotide sequence is shown in Figure 2. SEQ ID NO:1 is an example of a mutant promoter sequence that has the entire 5 nucleotide span deleted. Operably linking the claimed nucleic acids upstream of an ica nucleic acid that encodes IcaA, IcaD, IcaB and IcaC results in enhanced production of poly-N-acetyl glucosamine. The nature and identity of IcaA, IcaD, IcaB and IcaC gene products is known in the art as is their role in the synthesis of poly-N-acetyl glucosamine.

The claims recite isolated nucleic acids that hybridize to SEQ ID NO:2 but that comprise a mutation in at least two nucleotides in the 5 nucleotide span, and isolated nucleic acids that are fragments of SEQ ID NO:1 that span the 5 nucleotide deletion. The claimed nucleic acids enhance the production of the poly-N-acetyl glucosamine when they are operably linked to an ica nucleic acid that encodes IcaA, IcaD, IcaB and IcaC, as compared to poly-N-acetyl glucosamine production when the wildtype promoter (SEQ ID NO:2) is operably linked to the ica nucleic acid.

The claims are now amended to recite a particular polysaccharide (i.e., poly-N-acetyl glucosamine) and a particular ica nucleic acid (i.e., one that encodes IcaA, IcaD, IcaB and IcaC). The polysaccharide and the ica nucleic acid are recited in the specification and both are also known in the art. (See for example SEQ ID NO:3; GenBank Accession No. AF086783; McKenney et al., *The ica Locus of Staphylococcus epidermidis Encodes Production of the Capsular Polysaccharide/Adhesin*, Infection and Immunity, 66(10):4711-4720, 1998; and

Cramton et al., *The Intercellular Adhesion (ica) Locus is Present in Staphylococcus aureus and is Required for Biofilm Formation*, Infection and Immunity, 67(10):5427-5433, 1999.) The claims therefore no longer recite "any polysaccharide" nor "any ica nucleic acid".

The specification together with the knowledge in the art provides the guidance required to practice the invention. The Examiner states that the specification provides examples relating to SEQ ID NO:2 but does not provide guidance, prediction and working examples for making and/or using the claimed nucleic acid molecules. Respectfully, SEQ ID NO:2 is the wild type promoter and it is not embraced by the claims. The Examples compare biofilm production (as a readout of poly-N-acetyl glucosamine production) using mutant and wildtype SEQ ID NO:2. SEQ ID NO:1 is a mutant of SEQ ID NO:2. The Examples demonstrate that overproduction of poly-N-acetyl glucosamine by the S. aureus MN8m strain was due to the presence of the 5 nucleotide deletion in the ica promoter (as found in SEQ ID NO:1 and not SEQ ID NO:2). The Examples also demonstrate that overproduction of poly-N-acetyl glucosamine can be induced by substituting the 5 nucleotide wild type sequence (i.e., TATTT) with another 5 nucleotide sequence (e.g., ATAAA, as shown in strain pSUB).

The Examiner focuses on the nature and identity of the "specific enzyme and/or proteins involved in overproduction" of poly-N-acetyl glucosamine. Applicant considers this emphasis misplaced. The nature and identity of the IcaA, IcaD, IcaB and IcaC gene products is known, as is their role in poly-N-acetyl glucosamine synthesis. (See for example GenBank Accession No. AF086783, McKenney et al., *The ica Locus of Staphylococcus epidermidis Encodes Production of the Capsular Polysaccharide/Adhesin*, Infection and Immunity, 66(10):4711-4720, 1998; and Cramton et al., *The Intercellular Adhesion (ica) Locus is Present in Staphylococcus aureus and is Required for Biofilm Formation*, Infection and Immunity, 67(10):5427-5433, 1999.) Notwithstanding this however the claims recite a nucleic acid that encodes these gene products, and the specification together with the art provides the sequence of that nucleic acid. The Examples demonstrate that the mutant promoter sequences affect transcription from such nucleic acids and ultimately lead to overproduction of poly-N-acetyl glucosamine. The Examiner is apparently requesting that the claims recite the mechanism through which such overproduction is effected. Respectfully, neither an understanding of mechanism nor its recitation in the claims is a prerequisite for patentability.

The person of ordinary skill is able to practice the claimed invention based on the guidance provided by the specification and the state of the art without undue experimentation.

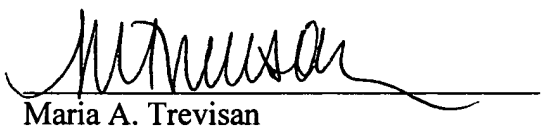
Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, enablement, is respectfully requested.

CONCLUSION

Applicant respectfully requests reconsideration. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825, under Docket No. B0801.70256US01.

Respectfully submitted,



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